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KAMRIN T. MACKNIGHT
GENENCOR INTERNATIONAL, INC.
925 PAGE MILL ROAD
PALO ALTO, CA 94304-1013

EXAMINER

SIMS, JASON M

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,255

Applicant(s)

AEHLE ET AL.

Examiner

Jason M. Sims

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 6/11/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 6/11/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claim 6 has been withdrawn as being drawn to a non-elected group with traverse in the response filed 8/21/2006.

Claims 1-5 and 7-15 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

Response to Arguments:

Applicant's arguments, filed 6/11/2007, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments. Therefore the rejections have been withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is drawn to a process and/or system. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and

tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be

"tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claim 1 does not produce a tangible result. The instant claims have been amended to comprise a resulting step of "providing said at least one initial hit." However, the term providing does not appear to be specifically limiting to statutory subject matter and is broadly and reasonably interpreted, for example, as reading on outputting the initial hit to another computer wherein the outputted result is the initial data used for another data manipulation method prior to being output again. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display, or to a user, or by including a final resulting step of a physical transformation, if such wording is supported by the instant specification.

Response to Arguments:

Applicant's arguments filed 6/11/2007 with respect to the rejection of claim 1 under 35 USC 101 as being drawn to non-statutory subject matter have been fully considered but they are not persuasive.

Applicant argues that the amendment to comprise a resulting step of "providing said at least one initial hit" renders the claim as being drawn to statutory subject matter.

Applicant's arguments are not found persuasive because the term providing does not appear to be specifically limiting to statutory subject matter and is broadly and reasonably interpreted, for example, as reading on outputting the initial hit to another

computer wherein the outputted result is the initial data used for another data manipulation method prior to being output again.

Claim Rejections - 35 USC § 102

The following rejection is being maintained:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 5 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crameri et al. (US P/N 6, 368, 861).

The claims are directed to a method for combinatorial consensus mutagenesis comprising of starting with a gene of interest, identifying homologs, aligning the sequences to identify consensus mutations, produce a combinatorial consensus library, and screen the library for an initial hit.

Crameri et al. teaches claim 1 and 10 at col. 2, lines 49-53, col. 4, lines 33-37, col. 7, lines 29-36, col. 8, lines 65-67, col. 9, lines 1-7 and lines 35-52, col. 10, lines 62-67, col. 11, and col. 13 lines 10-12. Crameri et al, at col. 7 discusses using oligonucleotides corresponding to at least one region of diversity, which represents selecting a gene of interest. Crameri et al., at col. 7-11, further discusses aligning nucleic acid sequences using available computer software and specifically at col. 9, Crameri et al. discusses using BLAST and other specific alignment algorithms and

tools, which represents generating a multiple sequence alignment of at least two homologs and a starting gene of interest. Crameri et al., at col. 2, discusses a method that provides a population of recombined nucleic acids where the members have consensus region subsequences derived from a plurality of homologous target nucleic acids, which represents a production of a combinatorial consensus library. Crameri et al. at col. 13 discusses screening methods for the combinatorial library. Crameri et al. at col. 4 discusses the said methods for homologous target sequences in regions that are overlapping or non-overlapping, which represents regions of homologs that are not part of a consensus sequence.

Crameri et al. teaches claims 2-4 and 11-14 at col. 10 and col. 13, lines 42-57. Crameri et al. discusses producing and sequencing improved clones from the cited inventive methods and producing a library of said improved clones, which represents sequencing at least one initial hit, identifying improving mutations and generating enhanced combinatorial consensus libraries and sequencing improved hits. Crameri et al. discusses doing the performing the above methods multiple times until desired properties result, which represents performing the methods of claims 2 and 3 more than once and producing improved sequence hits according to methods of claims 2 and 3.

Crameri et al. teaches claim 5 at col. 33, lines 55-67 and col. 34, lines 1-6. Crameri et al. discusses screening techniques that depend on what property or characteristic is desired such as stability-conferring sequences, which represents hits that are stabilized variants of said starting gene.

Crameri et al. teaches claim 15 at col. 4, lines 10-15, col. 8, lines 35-38, col. 10, lines 63-67, col. 11, and col. 12, lines 1-11. Crameri et al. discusses the products and compositions resulting from above said methods such as a library of nucleotides as discussed, which represents the production of a combinatorial consensus mutagenesis library according to the method of claim 1 of the instant application.

Response to Arguments:

Applicant's arguments, filed 6/11/2007, with respect to the rejection of claims under 35 USC 102 have been fully considered, but are not found persuasive.

Applicant argues that the claim approach is essentially the inverse of the teaching of the prior art reference cited, Crameri et al. Applicant specifically states that the instant claimed invention uses homology alignments to remove diversity opposed to the reference, which uses the alignments to incorporate more diversity into their libraries.

Applicant's argument is not found persuasive because applicant's arguments are not commensurate in scope with the claim language. The claim language states using a homology alignment to identify consensus mutations and to produce a combinatorial consensus mutagenesis library. Nothing in the claim language indicates that diversity is being reduced based on the homology alignment as applicant states in their arguments.

Applicant further argues that the useless residues are neglected in the presently claimed method.

Applicant's arguments again are not found persuasive as they are not commensurate in scope with the claim language, which does not state anything about what happens with the useless residues.

Applicants further allege that the methods of the present invention are necessarily focused on a few useful amino acid segments.

Applicant's allegations again are not found persuasive as they are not commensurate in scope with the instant claim language.

Applicant alleges that in the presently claimed method, random libraries are generated first in order to obtain knowledge regarding the effect of single mutation via screening and then the second round is only used to combine the best hits through random mutagenesis.

Applicant's arguments are not found persuasive as they are again not commensurate in scope with the instant claim language. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., random libraries are generated first in order to obtain knowledge regarding the effect of single mutation via screening and then the second round is only used to combine the best hits through random mutagenesis are not recited in the rejected claim(s)). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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// Jason Sims //

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Michael Borin", written over the printed name.